

### **Remarks/Arguments:**

Claims 1-16 are pending in the instant application.

### **Information Disclosure Statement**

In the Office Action, the Examiner stated that the information disclosure statement (IDS), filed on 03/24/2005 had been considered (in part).

The undersigned telephoned the Examiner on 16<sup>th</sup> March 2006 and the Examiner indicated that she had in fact consider all the references submitted and that the "in part" limitation was a typographical error. Applicants kindly ask the Examiner to reiterate (for the record) in the next communication from the USPTO that all the references submitted have been considered.

### **Priority**

The Examiner acknowledges Applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d) by application no. 0205170.4 filed in the United Kingdom Patent Office on 03/06/2002, which papers have been placed of record in the file. The Examiner states that the application names an inventor or inventors named in the prior application.

Applicants draw the Examiner attention to the fact that no inventors were in fact named in the earlier application – a practice in accordance with British law. The earlier application GB 0205170.4 was filed in the name of AstraZeneca AB.

Applicants remind the Examiner of the following section of 35 U.S.C. 119:

#### ***35 U.S.C. 119 Benefit of earlier filing date; right of priority.***

*(a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country.... (emphasis added)*

AstraZeneca AB was entitled to file the GB priority application because it derives legal entitlement by virtue of:

- (i) contracts of employment between the inventors and AstraZeneca UK Limited; and
- (ii) an agreement between AstraZeneca UK Limited and AstraZeneca AB that provides that inventions are jointly beneficially owned by AstraZeneca UK Limited and AstraZeneca AB and that patent property can be applied for in either name.

Applicants respectfully submit that the present situation fulfills the criteria of 35 U.S.C. 119 (a)-(d) and is thus our application is entitled to priority, but not because the application names an inventor or inventors named in the prior application.

### **Obviousness Double Patenting**

Claims 1-11 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-5 and 7 of co-pending U.S. Patent Application 10/344,506 ('506 App.). This is a provisional double patenting rejection since the conflicting claims have not yet been patented as of the date of this action.

On page 2 of the Office Action the Examiner states that:

*The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent.....*

Applicants agree with this statement, but do not believe it applies here. In the present situation an initial inventive contribution to the art was made and a patent application ('506) was filed. After this initial filing Applicants developed the initial contribution and made further specific examples within the small portion of the original filing that is embraced by the present filing. Applicants believe that we are not attempting to obtain an "unjustified or improper timewise extension" to our right to exclude monopoly, but are in fact attempting to obtain patent protection for the subsequent, additional, inventive contribution to the art.

The Examiner attention is drawn to the MPEP at chapter 804 under "II. Requirements of a Double Patenting Rejection (Including Provisional Rejections)"

*Dominance and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.... (emphasis added)*

In the Office Action the Examiner repeatedly makes reference to the fact that the instant claims are "more specific". Applicants respectfully suggest to the Examiner that she is in fact referring to dominance of the earlier application over the present application rather than double patenting. This is in fact reflected by the Examiners own statement on page 4 of the official action where she states:

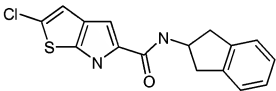
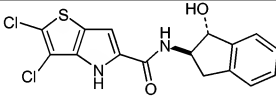
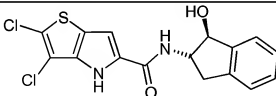
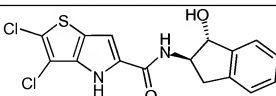
*Although, the instant application differs in that it is more specific, the claims of both applications overlap and one skilled in the art would have found this variation obvious when faced with the co-pending application because both compounds are used for the same pharmacological use so one skilled in the art would expect similar properties and results.*

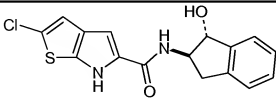
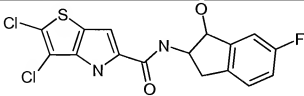
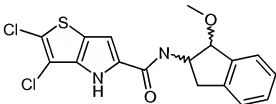
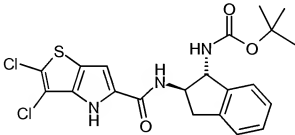
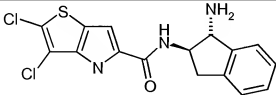
Again, Applicants respectfully point out that the Examiner is referring to dominance not double patenting, which, as outlined in the MPEP, is not *per se* a reason to raise a double patenting rejection.

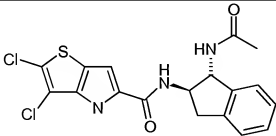
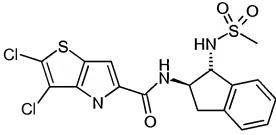
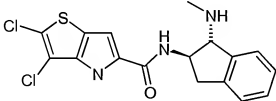
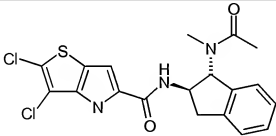
Finally the Examiner states on page 4 of the Official action that

*In addition, in the specification, starting on page 69, of the '506 App. the following compounds are the same compounds found in the instant application : Examples 112, 133-136, 138, and 148-154.*

Applicants respectfully disagree for the following reasons:

Ex	Structure	Not within the present claims because
112		The indanyl ring is unsubstituted. The present claim 1 has a mandatory Y substituent on this ring.
133		proviso vii
134		proviso vii
135		proviso vii

Ex	Structure	Not within the present claims because
136		proviso viii
138		proviso ix
148		proviso x
149		proviso i
150		proviso ii

Ex	Structure	Not within the present claims because
151		proviso iii
152		proviso iv
153		proviso v
154		proviso vi

The double patenting rejection remains provisional inasmuch as no claims have issued from or have been allowed in copending Application No. 10/344,506. However, Applicants respectfully request that the Examiner withdraws the rejection in view of our arguments above.

#### Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the specification while being enabled for treating certain glycogen phosphorylase activity, such as certain types of type 2 diabetes does not enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Following the conversation between the Examiner and the undersigned on March 16<sup>th</sup> 2006, Applicants understand that the Examiner intended this rejection to be made in relation to claim 14 and that claim 15, which is limited to type 2 diabetes only, would be in fact be acceptable. Applicants have duly cancelled claim 14 and consider that they have overcome this rejection.

### **Objections**

Claims 12 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

In view of the arguments above Applicants believe that they have overcome this rejection.

### **Other Amendments**

Applicants have taken this opportunity to make some additional amendments.

#### **Claim 1 and the specification**

Claim 1 has been amended to restrict the values of R<sup>6</sup> and R<sup>7</sup> to be hydrogen or chloro. Basis for this amendment is to be found in paragraph [0138] and [0139] of the specification.

In addition certain brackets were missing from some of the compounds in the provisos of claim 1. These have been amended and the corresponding paragraphs in the specification have also been amended. In the specification certain semi-colons were missing from the provisos – these have also been corrected. Applicants submit that these are minor typographical corrections.

#### **Claim 12 and the specification**

Certain typographical errors in claim 12 have been amended. Specifically missing and incomplete brackets have been corrected. Applicants consider these amendments minor corrections that require no further justification. The corresponding paragraphs in the specification have also been amended.

#### **Examples 40 and 41**

Applicants have also corrected an error in two of the names - Examples 40 and 41. In both the names the stereochemistry is written incorrectly. In paragraph [0798] of the specification the stereochemistry of these two compounds is incorrectly labeled as S:

Example 40: *N*-{[(**1S,2S**)-1-[[[(**2S**)-2-(*tert*-Butoxycarbonylamino)-2-carbamoylacetyl]amino]-2,3-dihydro-1*H*-inden-2-yl]-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide

Example 41: *N*-{[(**1S,2S**)-1-[(2-(*tert*-Butoxycarbonylamino)acetylamino)-2,3-dihydro-1*H*-inden-2-yl]-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide

However the starting material for these two examples is given as

*N*-{[(**1R,2R**)-1-amino-2,3-dihydro-1*H*-inden-2-yl]-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide (Method 21)

Method 21 is also drawn as the R stereochemistry in paragraph [0917].

Furthermore Example 40 is the starting material for Example 43 (paragraph [0801]):

Example 43: *N*-{[(**1R,2R**)-1-[[[(**3R**)-3-Amino-3-carbamoylpropanoyl]amino]-2,3-dihydro-1*H*-inden-2-yl]-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide

Example 43 is also drawn as the R stereochemistry.

Example 41 is the starting material for Example 44 (paragraph [0804]):

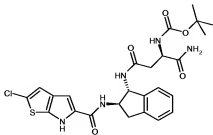
Example 44: *N*-{[(**1R,2R**)-1-[(Aminoacetyl)amino]-2,3-dihydro-1*H*-inden-2-yl]-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide

Example 44 is also drawn as the R stereochemistry.

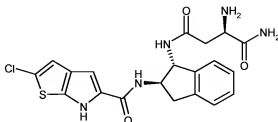
Applicants believe that since the starting material and the final product in this synthesis chain are consistently correctly listed and drawn as the R stereochemistry that the correction of the stereochemistry of the compound in the middle of the synthetic route is one that would be obvious to the skilled person. Applicants respectfully ask that they are allowed to make this amendment.

There is also an additional error in the name of Example 40. The structure of Example 40 is correct in the table (page 45 of the specification) but the name is wrong.

Example 40 has the following structure:



As stated above Example 40 is the starting material for Example 43 which has the following structure (paragraph [0800]):



Example 43 is a deprotection of the "boc" compound Example 40.

However the name of Example 40 is incorrectly given as the acetyl:

*N*-((1*S*,2*S*)-1-[[2(*S*)-2-(*tert*-Butoxycarbonylamino)-2-carbamoyl**acetyl**]amino]-2,3-dihydro-1*H*-indene-2-yl)-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide

where the name should in fact be the propanoyl:

*N*-((1*R*,2*R*)-1-(((3*R*)-3-(*tert*-butoxycarbonylamino)-3-carbamoylpropanoyl)amino)-2,3-dihydro-1*H*-inden-2-yl)-2-chloro-6*H*-thieno[2,3-*b*]pyrrole-5-carboxamide.

By analogy with the argument above Applicants submit that since the structure is correct in the table on page 45 and that it is an intermediate in the synthesis of Example 43 which is both named and drawn properly in the specification that this correction is an obvious one. Applicants respectfully ask that they are also allowed to make this amendment.

The amendment has been made in claim 12 and in the places it appears in the specification.

## New Claim 17

Finally applicants have added a new claim, Claim 17, directed towards the compounds described in Method 21 and 22. Applicants believe that there is adequate basis for this claim in the specification.

The above amendments have been made without prejudice to Applicants right to prosecute any cancelled subject matter in a timely filed continuation application.

Applicants believe the application is in condition for allowance, which action is respectfully requested.



Application No.	10/506,746
Amendment Dated	03/29/2006
Reply to Office Action of	12/29/2005

Although Applicants believe no fees are due, the Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. 100667-1P US.

Although Applicants believe no excess claim fees are due, the Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. 100667-1P US.

Respectfully submitted,

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